REMARKS

Claims 28-42, 44-46 and 48-50 are presently pending. Support for amendments to Claims 28 and 50 is found in the Specification as filed, for example at paragraph [0013]. No new matter has been added herewith. The following addresses the substance of the Office Action.

Indefiniteness

Claims 28-42, 44-46 and 48-50 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 28 recited "heterophilic antibodies" in line 3, and the Examiner indicated that there is no commonly accepted definition for the term "heterophilic antibody". Since the phrase "heterophilic antibody" has historically had different meanings, without acquiescing, the Applicant has amended Claim 28 by deleting recitation of "heterophilic antibodies". Instead of using the term "heterophilic antibodies," amended Claim 28 recites "A method for reducing interference during an immunoassay of a sample from a patient that is caused by specific, yet undesirable binding of an antibody in the sample to an antibody used in the immunoassay," as described in Paragraph [0013] of Applicants' specification. Accordingly, the claims are believed to be in compliance with the requirements of 35 U.S.C. § 112, second paragraph and the Applicant respectfully requests that the rejection be withdrawn.

Anticipation

Figard

Claims 28, 32, 34-38, 42 and 48 were rejected under 35 U.S.C. § 102(b) as being anticipated by Figard (U.S. Patent No. 5,616,460). The Examiner noted that Figard discloses an aqueous composition suitable for use as a buffer in an immunoassay method, wherein the composition comprises a biological buffer, ethylene glycol and a detergent. Figard teaches that the sample may contain non-specific, antibodies that adhere to the solid phase in the immunoassay. However, Figard does not disclose a method of reducing interference in an immunoassay of a sample from a patient that is caused by specific, yet undesirable binding of an antibody in the sample to an antibody used in the immunoassay. Such interfering antibodies are typically anti-animal antibodies (e.g., human anti-mouse antibodies), which disadvantageously bind to antibodies used in an immunoassay.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367,

1379 (Fed.Cir. 1986). "[A]nticipation requires that all of the elements and limitations of the claim are found within a single prior art reference." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). Since Figard does not disclose a method of reducing interference in an immunoassay of a sample from a patient that is caused by specific binding of an antibody in the sample to an antibody used in the immunoassay, the reference does not anticipate the claimed methods. Accordingly, the Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

Siedel et al.

Claims 28, 29, 30-42, 44-46, 48-49 and 50 were rejected under 35 U.S.C. § 102(b) as being anticipated by Siedel et al. (U.S. Patent No. 4,485,177). The Examiner noted that Siedel et al. teaches a reagent suitable for use in an immunoassay method, wherein the reagent comprises a buffer, a non-ionic detergent and polyethylene glycol. The Examiner concluded that, since the reaction mixture of Siedel et al. comprises the same reaction components as in the presently claimed methods, it would inherently reduce unspecific binding or reduce non-specific interference by heterophilic antibodies.

As noted above, since the phrase "heterophilic antibody" has historically had different meanings, the Applicant has deleted the term "heterophilic antibody" and has recited "A method for reducing interference during an immunoassay of a sample from a patient that is caused by specific, yet undesirable binding of an antibody in the sample to an antibody used in the immunoassay". Whether Siedel et al. inherently reduces unspecific binding is not relevant to the presently pending claims, which actively recite a reduction in specific binding. Accordingly, the Siedel et al. reference cannot anticipate the presently pending claims.

Moreover, the presently pending claims are nonobvious over the Siedel et al. reference. The Applicant has surprisingly determined that specific binding of an antibody in a sample to an antibody used in an immunoassay can be reduced by the presently claimed methods. Nothing in the disclosure by Siedel et al. would have given one of ordinary skill in the art any reason to believe that such specific, yet undesirable binding could be reduced by the presently claimed method. Siedel et al. discloses at column 6, lines 41-45 that polyethylene glycol is preferably used to promote immunoprecipitation and Example 2 of the reference, at column 10, lines 25-37 discloses an immunoprecipitation (IP) incubation buffer that contains a buffer and Tween 20. However, there would have been no reason for the skilled artisan to attempt to eliminate

interference due to specific binding of antibodies in a sample to antibodies used in an immunoassay by means of the presently claimed methods. In light of the amendments to Claim 28, the reference neither anticipates nor renders obvious the presently claimed methods, since nothing in the disclosure by Siedel et al. would have given one of ordinary skill in the art any reason to believe that specific binding of an antibody in a sample to an antibody used in the immunoassay could be reduced by the presently claimed method. Accordingly, the Applicant respectfully requests that the rejection be withdrawn.

Obviousness

Salonen

Claims 28, 32-42, 48-49 and 50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Salonen (GB 2062224A). Salonen discloses an immunoassay method that comprises reaction of a binding pair member in a solution comprising phosphate buffer, polyethylene glycol (i.e., Compound A), a non-ionic detergent (e.g., Tween 20) and NaCl. Salonen discloses that polymers such as polyethylene glycol exert a promoting effect on the interaction between soluble antigens and antibodies, apparently by steric exclusion of the immune complexes from the domain of the polymer. Thus, the method of Salonen accelerates immunological antigen-antibody reactions. The Examiner concluded that, since the reaction mixture of Salonen comprises the same reaction components as in the presently claimed methods, it would inherently reduce non-specific interference by heterophilic antibodies. Referring to Kaplan (1999 *Clinical Chemistry* **45**:616-618), the Examiner defined "heterophilic antibodies" as being weak antibodies with multispecific activities against poorly defined antigens.

As noted above, the Applicant has amended Claim 28 by removing recitation of "heterophilic antibodies". Instead, the amended claim recites "A method of reducing interference in an immunoassay of a sample from a patient that is caused by specific, yet undesirable binding of an antibody in the sample to an antibody used in the immunoassay. Nothing in the disclosure by Salonen would have given one of ordinary skill in the art any reason to believe that specific binding of an antibody in a sample to an antibody used in the immunoassay could be reduced by the presently claimed method. The goal of the method of Salonen is to accelerate immunological antigen-antibody reactions. Thus, there would have been no reason for the skilled artisan to attempt to eliminate interference due to specific binding of antibodies in a sample to antibodies used in an immunoassay by means of the presently claimed methods. In light of the amendments

to Claim 28 and the preceding remarks, the claimed methods are not *prima facie* obvious and the Applicant respectfully requests that the rejection be withdrawn.

Figard

Claims 33, 39, 40, 44-46 and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Figard (*supra*). The Examiner stated that, although the reference does not mention the ratio of non-ionic detergent to ethylene glycol and ionic strength, the adjustment of particular working conditions is deemed merely a matter of judicious selection and routine optimization. However, as discussed above, Figard does not disclose a method of reducing interference in an immunoassay of a sample from a patient that is caused by specific binding of an antibody in the sample to an antibody used in the immunoassay. Thus, the reference neither anticipates nor renders obvious the presently claimed methods, since nothing in the disclosure by Figard would have given one of ordinary skill in the art any reason to believe that specific binding of an antibody in a sample to an antibody used in the immunoassay could be reduced by the presently claimed method. Accordingly, the Applicant respectfully requests that the rejection be withdrawn.

Stewart et al.

Claims 28-40, 41-42, 44-46, 48 and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stewart (U.S. Patent No. 6,503,702). The Examiner noted that Stewart teaches an immunoassay buffer system comprising a buffer, a detergent, a salt, a stabilizing agent and a protein, wherein the stabilizing agent can be polyethylene glycol. However, the reference does not disclose a method of reducing interference in an immunoassay of a sample from a patient that is caused by specific binding of an antibody in the sample to an antibody used in the immunoassay. Thus, Stewart does not render obvious the presently claimed methods, since nothing in the disclosure by the reference would have given one of ordinary skill in the art any reason to believe that specific binding of an antibody in a sample to an antibody used in the immunoassay could be reduced by the presently claimed method. Accordingly, the Applicant respectfully requests that the rejection be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this

application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: May 19, 2010

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